

**Navajo Nation Human Research Review Board
Institutional Review Board Meeting Agenda**

DATE: June 21, 2016

TIME: 9:00AM

PLACE: NDOH Conference Room
Window Rock, AZ

MEMBERS:

Dr. Mark C. Bauer, Ph.D. - Scientific Education
Beverly Becenti-Pigman, Chairperson - Community
Dr. David Begay, Ph.D. - Scientific Education
Rebecca Izzo-Manymules, MPH, Ph.D. (C) - Education
Ursula Knoki-Wilson, MPH, BSN – Nursing
Wallace McGilbert - Community
Dr. Raymond Reid, MD - Medicine
Dr. Kalvin White, Ph.D. - Scientific Education
Mike Winney, Staff

OLD BUSINESS:

- I. Meeting Call to Order
- II. Roll Call
 - Invocation
 - Introductions
- III. Review and Approval of Agenda
- IV. Review and Approval of February 16, 2016 Meeting Minutes

NEW BUSINESS:

- V. Serious Adverse Events (SAEs)
- VI. Quarterly Reports
- VII. New Presentations
- VIII. Returning Presentations
- IX. Noon Hour Discussion:
- X. Manuscripts / Abstracts
- XI. Announcements / Adjournment

**Navajo Nation Human Research Review Board
IRB 6/21/2016 Meeting Agenda**

VII. NEW PRESENTATION(S)

1. NNR-16.247T PI: Bender, Bruce G. Ph.D.
Creating an asthma collaboration to reduce childhood asthma disparities on the Navajo Nation
Reason on Agenda: New Title
Description: Request Review and Approval of New Study
2. NNR-16.248T PI: Scheer, Helen Hood
Navajo Resilience Project
Reason on Agenda: New Title
Description: Request Review and Approval of New Title

VIII. RETURNING PRESENTATION(S)

1. NNR-05.174 PI: Walkup, John MD
In-home Prevention of Substance Abuse Risk in Navajo Teen Families
Reason on Agenda: Conference Presentation
Description: Request Review and Approval of Conference Presentation Abstract Titled: Examining a Home-Visiting Program's Benefits for Children of Mothers with High Risk Substance Abuse at The National Research on Early Childhood in July 11-13, 2016 in Washington, D.C.
2. NNR-05.175 PI: Mohs, Kimberly Dr.
Navajo Area Indian Health Services - Cardiovascular Risk Reduction Demonstration Project
Reason on Agenda: Quarterly Report
Description: Request Review and Acceptance of Quarterly Report ending April 2016.
3. NNR-07.198 PI: McGrath, Jane W. MD
Envision New Mexico Pediatric Overweight Learning Collaborative
Reason on Agenda: Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering December 17, 2015- March 16, 2016 period.
4. NNR-09.241 PI: Overman, Barbara Ph.D.
Giving Voice to Health Values from within the Navajo Culture
Reason on Agenda: Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering February 1 - April 31, 2016 period.
Reason on Agenda: Conference Presentation
Description: Request Review and Approval of Abstract for Conference Presentation on March 30 - April 2, 2017, 7th International Meeting on Indigenous Child Health in Denver, CO

5. NNR-09.245 PI: Wiggins, Charles Ph.D.

Understanding lung cancer risk among Navajo former uranium miners

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering November 19, 2015 - February 19, 2016 period.

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Request for Continuation of Study covering May 19, 2016 - May 19, 2017 period.

6. NNR-10.268 PI: Braun, Patricia MD

Preventing Caries in Preschoolers: Testing a Unique Service Delivery Model in American Indian Head Start Programs

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Reports covering 1) November 1, 2015 - January 31, 2016, 2) February 1, - April 30, 2016 period

7. NNR-11.150 PI: Shin, Sonya MD

Evaluating the Navajo Community Outreach and Patient Empowerment (COPE) Program

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering March 15 - June 21, 2016 period.

8. NNR-15.199 PI: Shin, Sonya MD

REACH for Healthy Navajo Communities.

Reason on Agenda: Addendum

Description: Request Acceptance and Approval of Addendum of Supporting Resolution to Study from: 1) Lukachukai Chapter, 2) Oljato Chapter; 3) Counselor Chapter; 4) Rough Rough Chapter 5) Shiprock Chapter; 6) Red Mesa Chapter

Reason on Agenda: Consent Modification

Description: Request Acceptance and Approval of Revision of Verbal Consent Form.

Reason on Agenda: Addition of Co-Investigator

Description: Request Acceptance and Approval of Adding Ms. Joan VanWassenhove-Paetzold, MPH and PhD. candidate as Co-Principal Investigator: 1) Resume, 2) Letter of Interest, 3) Letter of Support from Dr. Shin.

9. NNR-11.152 PI: Leischow, Scott J. Ph.D.

Networks among Tribal Organizations for Clean Air Policies

Reason on Agenda: Annual Report – **TABLE Use Packet from April 19th and May 17th, meeting.**

Description: Request Acceptance and Approval of Annual Report covering June 16, 2015 - March 23, 2016 period. (approval 6/16/15-6/16/16)

Reason on Agenda: Progress Report

Description: Request Acceptance and Approval of Report on the Traditional Healer Digital Story Projects and Traditional Healer Oral Stories Transcripts.

10. NNR-15.203 PI: Leischow, Scott J. Ph.D.

Standardized Tobacco Assessment for Retail Settings - Tribal Commercial Tobacco (STARS-TCT)

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering May 19, 2015 - May 19, 2016 period.

Reason on Agenda: Approval for Dissemination

Description: Request the Acceptance and Approval of Dissemination of Regulating the Sales & Marketing & Tobacco letter and handout.

11. NNR-11.323 PI: Lewis, Johnnye L. Ph.D.

Navajo Birth Cohort Study (NBCS)

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering February 23 - May 22, 2016 period.

12. NNR-15.214 PI: Lewis, Johnnye L. Ph.D.

Wood Stove Interventions and Child Respiratory Infections in Rural Communities

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 21 - April 20, 2016 period.

13. NNR-11.342 PI: O'Connell, Joan M. Ph.D.

Comparative Effectiveness of Healthcare Delivery Systems for American Indian and Alaska Native using Enhanced Data

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering June 2015 - May 2016 period,.

Reason on Agenda: Progress Report

Description: Request Review and Acceptance of Progress Summary Report of Study.

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering March 2016 - May 2016 period.

Reason on Agenda: Progress Report;

Description: Request Review and Acceptance of Project Overview and most recent protocol approval.

Reason on Agenda: Addendum

Description: Request Acceptance and Approval of Addendums to Protocol Continuation: 1) COMIRB, 2) I.H.S. IRB Approval; 3) I.H.S. Data Agreement; 4) Letters of Support from Chinle and Tuba City Service Units.

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Request for Continuation of Study covering 5-15-2016 - 5-16-2017 period.

14. NNR-13.160 PI: Greyeyes, Wendy

The Language of Enumeration in Native America: Tribal Knowledge, Tradition(s) and Transitions in Modern Indigenous

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering November 20, 2015 - February 19, 2016 period.

15. NNR-14.171 PI: Henderson, Davis E

CELF - 4 and PPVT - 4 among Navajo Students

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering March - May 2016 period.

16. NNR-14.175 PI: Lombard, Kevin A. Ph.D.

Where Health and Horticulture Intersect: A Navajo Wellness Collaboration

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering June 2015 - May 2015 period.

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Reports covering 1) May 1, 2015 - August 31, 2015, 2) September 1, 2015 - December 31, 2015; 3) January 1, 2016 - April 4, 2016 period.

Reason on Agenda: (Other)

Description: Request Review and Acceptance of Curriculum: Outline for 2015 Workshops # 4-7 and Closing 2016 Workshop.

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering June 2016 - June 2017 period.

17. NNR-14.186 PI: Emord, Patty

An Evaluation of the B9 Vitamin Initiative for Navajo Women of Child Bearing Age

Reason on Agenda: Progress Report

Description: Request Review and Acceptance of Executive Summary Report on Study.

Reason on Agenda: Approval for Dissemination

Description: Request Review and Acceptance of Data Dissemination Report.

18. NNR-14.189 PI: Kahn-John, Michelle Ph.D., RN

The Factor Structure of Six Cultural Concepts on Psychological Distress and Health Related Quality of Life in a Southwestern American Indian Tribe.

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Reports covering: 1) October 20, 2015 - December 31, 2015; 2) January 1 2016 - March 31, 2016, 3) April 1 - June 21, 2016 periods.

19. NNR-15.205 PI: Kahn-John, Michelle RN, Ph.D.

Qualitative Exploration of Dine Hozho: A Focused Ethnography

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Reports covering: 1) October 20, - December 31, 2015; 2) January 1, 2016 - March 31, 2016; 3) April 1 - June 21, 2016 periods.

20. NNR-15.201 PI: Bauer, Mark C. Ph.D

An Intervention to Promote Navajo Gardening, Nutrition, and Community Wellness

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of Modification of Questionnaires Survey.

21. NNR-15.207 PI: Shaughnessy, Richard Ph.D.

From Home to School: Tribal Indoor Air Quality Study

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Reports; 1) November 1, 2015 - January 31, 2016, 2) February 1 - April 30, 2016 period with Supporting Resolution from Shiprock Associated School, Inc.

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request from July 21, 2016 - July 21, 2017 period.

22. NNR-15.208 PI: Pollari, Lynette

Dine Cultural Sustainability through Settlement Form: "Finding Patterns for New Navajo Neighborhoods:

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering February 19, 2016 - May 19, 2016 period.

23. NNR-15.220 PI: Laughter-Begay, Lucy A.

Healthy and Hunger Free Kids Act Food Access Navigation Project Study

Reason on Agenda: Approval for Dissemination

Description: Request Review and Approval of Dissemination of Brochure.

24. NNR-15.225 PI: Hee Kim, Sang
Achieving Success by Promoting Readiness for Education and Employment
Reason on Agenda: Progress Report
Description: Request Review and Acceptance of Quarterly Report covering January 21 - April 20, 2016 period.
25. NNR-15.229 PI: Carre, Nancy C.
The Effect of Educational Narratives on High School Persistence among Navajo Girls
Reason on Agenda: Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering February 16, 2016 - May 16, 2016 period.
26. NNR-15.203 PI: Quintana, Eugenia.
Residential Wood Smoke Intervention Improving Health In Native American Populations
Reason on Agenda: Continuation Request
Request Acceptance and Approval of Continuation Request covering July 21, 2016 - July 21, 2017 period.
27. NNR-16.245T PI: Gittelsohn, Joel Ph.D.
Engaging Tribal Policy Makers to Sustain Improvements to the Food and Physical Activity in American Indian Communities (OPREVENT2)
Reason on Agenda: Addendum
Description: Request Acceptance and Approval of Addendum of Johns Hopkins IRB approval notice (per request by NNHRRB for full approval)
28. NNR-02.111 PI: Reid, Raymond MD
Effects of Maternal Influenza Vaccination on Respiratory Disease among Infants
Reason on Agenda: Continuation Request
Description: Request Acceptance and Approval of Study from August 20, 2016 - August 20, 2017 period.
29. NNR-04.151 PI: Santosham, Mathuram MD
A Phase 3 Study of MEDI-524 (Numax®), an Enhanced Potency Humanized Respiratory Syncytial Virus (RSV) Monoclonal Antibody, for the Prevention of RSV Disease Among Navajo and White Mountain Apache Infants in the Southwestern United States
Reason on Agenda: Continuation Request
Description: Request Acceptance and Approval of Continuation Request of Study covering September 21, 2016 - September 21, 2017 period.
30. NNR-09.253 PI: Reid, Raymond MD
Impact of 13-valent pneumococcal conjugate vaccine (PVC13) on pneumococcal disease and colonization among Native American communities
Reason on Agenda: Continuation Request
Description: Request Acceptance and Approval of Request Continuation of Study covering August 18, 2016 - August 18, 2017 period.
31. NNR-09.255 PI: Reid, Raymond MD
Pilot Study of the Association between Acute Gastroenteritis and Water Quality, Availability, and Handling Practices on the Navajo Nation
Reason on Agenda: Continuation Request
Description: Request Acceptance and Approval of Continuation Request of Study covering August 18, 2016 - August 18, 2017 period.

32. NNR-13.102 PI: Jones, Rachelle G. Ph.D. **PLEASE USE PACKET ITEM FROM MAY 17TH MEETING AGENDA - TABLED**
Maintaining Hozho: Preceptions of Physical Activity, Physical Education and Healthy Living Among Navajo High School Students
Reason on Agenda: Quarterly
Description: Request Review and Acceptance of Quarterly Report covering: 2015 4th Quarterly Report, and 2016 1st Quarterly Report.
Reason on Agenda: Continuation Request
Description: Request Acceptance and Approval of 1) Continuation Request covering 12/15/2105 -12/15/2016 period, 2- ASU Approval Notice.

FINAL REPORT

NNR-14.188 PI: Pindus, Nancy M.
Study of the Food Distribution Program on Indian Reservations.
Reason on Agenda: Final Report
Description: Request Acceptance and Approval of Final Report of Study.

X. MANUSCRIPTS

1. Prevention of Type 2 diabetes in American Indian Youth: Tribal Turning Point Pilot (NNR-13.158) – *Dr. D. Dabelea, MD, MPH*
2. Norovirus and Sapovirus epidemiology and strain characteristics among Navajo and Apache Infants (NNR-02.099) – *Dr. R.Reid, MD*
3. Navajo Traditional Healer Oral Study Project: Exploring Commercial Tobacco use in ceremonial setting (NNR-11.152) *Dr. S. Leischow, Ph.D.*

ABSTRACTS

1. Implementing an Electronic Risk Assessment Tool to Promote the use of Statin Therapy in Patients with Type 2 Diabetes attending a Primary Care Clinic. – *DeAnn Nelson*

XI. Announcements / Adjournment

Last page and end of Agenda